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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,840	02/11/2004	Raghavan Rajagopalan	MRD / 62DV	3029

7590 01/03/2007

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EXAMINER	
HAQ, SHAFIQUL	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/776,840	RAJAGOPALAN ET AL.	
	Examiner	Art Unit	
	Shafiqul Haq	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-39* is/are pending in the application.

4a) Of the above claim(s) *31-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/11/04, 4/25/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Election/Restrictions

1. Applicants' election of Group III, claims 37-39 filed November 11, 2006 in response to Office Action of October 4, 2006 is acknowledged and entered. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, the restriction requirement is deemed proper and is made FINAL.

   Accordingly, claims 31-36 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims cited supra be canceled in response to this Office action to expedite prosecution.

2. Claims 37-39 are examined on merits.

Information disclosure statement

3. NPL document cited in IDS (J.R in IDS filed 2/11/04) have not been considered because a copies of those document were not provided. In order to be in compliance with MPEP 609, III, A (2), applicants must provide copies of all of the references cited in the IDS. These references will become part of the official file of this application. Upon receipt of the missing documents, they will be considered by the examiner when preparing the next office action and a signed copy of form PTO-1449 will be provided with the next office action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 37 recites "Type 1 agent" and "Type 2 agents" in lines 3-4. It is not clear what compounds are encompassed by "Type 1 agents" and "Type 2 agents". Specification disclose Type 1 and Type 2 mechanism driven energy transfer from sensitizer for phototherapy but however, do not clearly define what compounds are encompassed by Type 1 and Type 2 agents. The chemical nature and structure of the "Type 1" and "Type 2" agents are also unclear.

7. Claim 37 recites the phrase "with sufficient power and fluence rate to cause necrosis or apoptosis of said target tissue" in lines 7-8. The phrase "sufficient power and fluence" is not defined or described in the specification and thus it is unclear what power range and fluence rate would be considered "a sufficient power and fluence rate" for causing necrosis or apoptosis.

8. Claim 38 recites the phrase "wherein said photosensitizing mixture coprises azides, phthalocyanines and porphyrins". It is unclear whether azides, phthalocyanines and porphyrins in the phorosensitizing mixture are in addition to Type 1 agents and Type 2 agents or they encompasses Type 1 and Type 2 agents recited in claim 37. If they encompasses Type 1 and Type 2 agents as recited in claim 37, it is unclear which

compounds are Type 1 agent and which compounds are Type 2 agents. It is also unclear what compounds are encompassed by the term "azides" as compounds encompassed by "azides" are not defined in the specification.

9. Claim 39 recites the phrase "comprising step of allowing said photosensitizing mixture to accumulate in said target tissue". In claim 37, step (b) comprises administering photosensitizing mixture to a target tissue. "Administering photosensitizing mixture to a target tissue" can be interpreted as allowing photosensitizing mixture to come in contact with a target tissue. It is unclear how claim 39 is different from claim 37 with respect to exposure of target tissue with the photosensitizing mixture. Appropriate clarification is required.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 37-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for dyes conjugated to azide group, does not reasonably provide enablement for all azide compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The term "azides" encompasses sodium azide, alkyle azide and other azide compounds. The specification provides guidance only for use of azide compounds wherein azide moiety is conjugated with a compound containing dye (dye-azide) (see summary of invention and page 9, lines 14-23), but there in no enablement in the specification for use of all other azide compounds such a sodium azide or alkyl azide. As described in specification, upon photoactivation of the dye, the azide moiety (N_3) produces nitrene useful for phototherapy. However, sodium azide or alkyl azide (not conjugated with a photoactive dye) will not be able to produce reactive nitrene intermediate and thus will not useful as phototherapeutic agent as described in claim 37.

Conclusions

12. The prior art made of record and not relied upon is considered pertiinent to applicant's disclosure.

Bodaness et al. (US 5,563,132) in a two-step cancer treatment method disclose administration of porphyrin or porphyrin like compounds (e.g. porphyrins, porphyrin derivatives, phthalocyanines, phthalocyanine derivatives) (Type II reagent that produce singlet oxygen) (see column 7, lines 1-15) and a peroxide compounds to cancer patient. Bodaness et al., however, do not disclose use of Type I reagent and exposure of target with the light of wavelength 300 to 950 nm.

Harth et al. (US 2003/0216795 A1) disclose activation of P. acne induced porphyrins (Type II agent) by exposure to light with 400-450nm that destroy P. acne

bacteria by the formation of peroxide (paragraph [0019]). Harth et al. however, do not disclose using type I reagent in combination of type II reagent.

Kayyem et al. (US 6,962,686 B2) disclose Type II therapeutic agent (e.g. porphyrins, hematoporphyrins, cyanines, acridines etc) for treatment of cancer but do not disclose using type I therapeutic agent in combination.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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